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APR - 2 2004

510(k) SUMMARY
PhotoMedex, Inc.
LaserPro CO_2 Carbon Dioxide Laser System

1. GENERAL

- *Submitter:* PhotoMedex, Inc.
  147 Keystone Drive
  Montgomeryville, PA, 18936

- *Contact Person:* Bob Rose
- *Date Prepared:* January 30, 2004

2. DEVICE NAME

- *Classification name:* Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)

- *Common or usual name:* Carbon dioxide laser

- *Trade or proprietary name:* LaserPro CO_2 Carbon Dioxide Laser System

3. PREDICATE DEVICES

Carbon Dioxide Laser Systems:

- Lumenis Modified Family of UltraPulse SurgiTouch CO_2 Laser Systems (K030147)

- Lumenis UltraPulse Encore Carbon Dioxide Laser and Delivery Device Accessories (K022060)

4. DEVICE DESCRIPTION

The PhotoMedex LaserPro CO_2 carbon dioxide laser system is designed to provide infrared laser power at a wavelength of 10,600nm which can be used for the procedures indicated in the next section. The system is comprised of the following main components:

- A laser console
- A laser console tower
- Display panel with soft-touch keypad control and separate Emergency Off button.
- Laser system microprocessor control electronics with operating software
- A seven segment counterbalanced articulated arm designed to accept the delivery accessories defined in CHART A located in the next section.
- A detachable covered footswitch.

5. INDICATIONS FOR USE

The Photomedex LaserPro CO_2 Carbon Dioxide Laser System, when used in conjunction with the identified delivery accessories (CHART A), is designed to deliver light energy and is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. Additionally, the LaserPro CO_2 Carbon Dioxide Laser System is indicated for use in specific surgical applications in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

CHART A: Delivery Accessories to be used with the LaserPro CO_2 Carbon Dioxide Laser System

Delivery Systems Used With the PhotoMedex LaserPro™ CO_2 Carbon Dioxide Laser System	Manufacturer's Model Number	Premarket Notification Clearance Number
Acutome® 100 CO_2 Laser Handpiece	0200-033-01	K942935
Accuscan® CO_2 Laser Scanner	0200-216-01	K953670
Acutome® 2000 CO_2 Laparoscopic Coupler	0200-044-01	K942868
Unimax® 2000 CO_2 Micromanipulator	0200-009-01C	K920821

6. SUBSTANTIAL EQUIVALENCE

The Photomedex LaserPro CO_2 Carbon Dioxide Laser System, when used in conjunction with the identified delivery accessories (CHART A) share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to the predicate devices which includes the Lumenis Modified Family of UltraPulse SurgiTouch CO_2 Laser Systems (K030147) and the Lumenis UltraPulse Encore Carbon Dioxide Laser and Delivery Device Accessories (K022060). In addition, a review of the predicate devices demonstrates that the PhotoMedex LaserPro CO_2 Carbon Dioxide Laser System, when used in conjunction with the identified delivery accessories is safe and effective as the predicate devices as they share equivalent optical wavelengths, and are used to perform the same indicated surgical procedures.

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7. SAFETY AND EFECTIVENESS; PRODUCT PERFORMANCE

The Photomedex LaserPro CO_2 Carbon Dioxide Laser System is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including 21 CFR 1040.10 & 1040.11, PART 820 – Quality System Regulation, EN60601-1, EN60601-1-2, EN60601-2-22, EN 60601-1-4, EN ISO 14971, IEC60825, and, UL2601-1 / UL60601-1 ensuring when used with the identified delivery accessories (CHART A), that it is both safe and effective for the medical applications indicated. No new clinical indications are to be provided by the introduction of LaserPro CO_2 Carbon Dioxide Laser System as compared to the predicates, which have previously demonstrated clinical effectiveness to the uses indicated.

8. CONCLUSIONS

Based on the information reviewed and provided within this application, PhotoMedex believes that the LaserPro CO_2 Carbon Dioxide Laser System is substantially equivalent to, and is safe and effective as the legally marketed predicate devices, the Lumenis Modified Family of UltraPulse SurgiTouch CO_2 Laser Systems (K030147) and the Lumenis UltraPulse Encore Carbon Dioxide Laser and Delivery Device Accessories (K022060) in that they share the same mechanisms for laser energy delivery and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Mr. Bob Rose
Director of Regulatory Affairs
and Quality Assurance
PhotoMedix, Inc.
147 Keystone Drive
Montgomeryville, Pennsylvania 18936

Re: K040234
Trade/Device Name: LaserPro® CO_2 Carbon Dioxide Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 30, 2004
Received: February 2, 2004

Dear Mr. Rose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040234

Device Name: LaserPro® CO_2 Carbon Dioxide Laser System

Indications For Use:

The PhotoMedex LaserPro CO_2 Carbon Dioxide Laser System, when used with the delivery accessories identified in the Users Instructions (used to deliver laser energy), is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

The LaserPro CO_2 Surgical Laser is indicated for use in the performance of specific surgical applications in aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery as follows:

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing;
- Laser derm-abrasion;
- Laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) for treatment of:

- wrinkles, rhytids, and furrows (including fine lines and texture irregularities).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040234

Indications for Use

510(k) Number (if Known): K040234

Device Name: LaserPro® CO_2 Carbon Dioxide Laser System

Indications For Use: Continued from previous page:

Dermatology & Plastic Surgery, continued

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart, and verruca seborrheica;
- vermillionectomy of the lip;
- cutaneous horns;
- solar/actinic elastosis;
- cheilitis, including actinic cheilitis;
- lentigines, including lentigo maligna or Hutchinson's malignant freckle;
- uneven pigmentation/ dyschromia;
- acne scars;
- surgical scars;
- keloids including acne keloidalis nuchae;
- hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telagiectaticum);
- tattoos;
- telangiectasia;
- removal of small skin tumors, including periungual (Koenen) and subungual fibmromas;
- superficial pigmented lesions;
- adenosebaceous hypertrophy or sebaceous hyperplasia;
- rhinophyma reduction;
- cutaneous papilloma (skin tags);
- milia;
- debridement of eczematous or infected skin;
- basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions;
- nevi, including spider, epidermal and protruding;
- neurofibromas;
- laser de-epithelialization;
- tricoepitheliomas;
- xanthelasma palpebrarurn;
- syringoma

Indications for Use

510(k) Number (if Known): K040234

Device Name: LaserPro® CO_2 Carbon Dioxide Laser System

Indications For Use: Continued from previous page:

Dermatology & Plastic Surgery, continued

Laser ablation, vaporization and/or excision for complete and partial nail matrixectomy

Vaporization/coagulation of:
- Benign/malignant vascular/avascular skin lesions;
- Moh's Surgery;
- lipectomy;
- verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungual warts;

Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation

Podiatry

Laser ablation, vaporization and/or excision of soft tissue for the reduction, removal, and/or treatment of:
- verrucae vulgares/plantar (warts), including paronychial, periungal, and subungual warts;
- fungal nail treatment;
- porokeratoma ablation;
- ingrown nail treatment;
- neuromas/fibromas, including Morton's neuroma;
- debridement of ulcers;
- other soft tissue lesions.

Genitourinary

Incision, excision and vaporization of soft tissue in genitourinary procedures. Applications include:
- benign and malignant lesions of external genitalia;
- condyloma;
- phimosis;
- erythroplasia

Indications for Use

510(k) Number (if Known): K040234

Device Name: LaserPro® CO_2 Carbon Dioxide Laser System

Indications For Use: Continued from previous page:

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology for treatment of:

- choanal atresia;
- leukoplakia, including oral, larynx, uvula, palatal, upper lateral pharyngeal tissue; nasal obstruction;
- adult and juvenile papillomatosis polyps;
- polypectomy of nose and nasal passages;
- lymphangioma removal;
- removal of vocal cord/fold nodules, polyps and cysts;
- removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;
- laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue;
- Zenker's Diverticulum/ pharyngoesophageal diverticulum [endoscopic laser-assisted esophagodiverticulostomy (ELAED)];
- stenosis, including subglottic stenosis;
- tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil ablation/tonsillotomy;
- pulmonary bronchial and tracheal lesion removal;
- benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial);
- benign and malignant lesions and fibromas (nose and nasal passages);
- benign and malignant tumors and fibromas (oral);
- stapedotomy/stapedectomy;
- acoustic neuroma in the ear;
- superficial lesions of the ear, incl. chondrodermatitis nondularis chronica helices/Winkler's disease;
- telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue);
- cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea;
- myringotomy/tympanostomy (tympanic membrane fenestration);
- uvulopalatoplasty (LAUP, laser UPPP);
- turbinectomy and turbinate reduction/ablation;
- septal spur ablation/reduction and septoplasty;
- partial glossectomy;
- tumor resection on oral, subfacial and neck tissues;
- rhinophyma;
- verrucae vulgares (warts);
- gingivoplasty/gingivectomy

Indications for Use

510(k) Number (if Known): K040234

Device Name: LaserPro® CO_2 Carbon Dioxide Laser System

Indications For Use: Continued from previous page:

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology (GYN) for treatment of:

- conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia VIN, VAIN);
- condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions;
- leukoplakia (vulvar dystrophies);
- incision and drainage (I&D) of Bartholin's and nubuthian cysts;
- herpes vaporization;
- urethral caruncle vaporization;
- cervical dysplasia;
- benign and malignant tumors;
- hemangiomas

GYN Laparoscopy

Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including GYN laparoscopy, for treatment of:

- endometrial lesions, including ablation of endometriosis;
- excision/lysis of adhesions;
- salpingostomy;
- oophorectomy/ovariectomy;
- fimbroplasty;
- metroplasty;
- microsurgery (tubal);
- uterine myomas and fibroids;
- ovarian fibromas and follicle cysts;
- uterosacral ligament ablation;
- hysterectomy

Indications for Use

510(k) Number (if Known): K040234

Device Name: LaserPro® CO_2 Carbon Dioxide Laser System

Indications For Use: Continued from previous page:

Neurosurgery

Laser incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of:

- **Cranial**
  - Posterior fossa tumors;
  - peripheral neurectomy;
  - arteriovenous malformation;
  - benign and malignant tumors and cysts [e.g. gliomas, menigiomas (including basal tumors),
  - acoustic neuromas, lipomas and large tumors];
  - pituitary gland tumors (transsphenoidal approach)

- **Spinal Cord**
  - incision/excision and vaporization of benign and malignant tumors and cysts;
  - Intra- and extradural lesions;
  - laminectomy/ laminotomy/ microdiscectomy

General and Thoracic Surgery

Incision, excision and vaporization of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include:

- debridement of decubitus ulcers, stasis, diabetic and other ulcers;
- mastectomy;
- debridement of burns;
- rectal and anal hemorrhoidectomy;
- breast biopsy;
- reduction mammoplasty;
- cytoreduction for metastatic disease;
- laparotomy and laparoscopic applications;
- skin tag vaporization;
- atheroma;
- abscesses;
- other soft tissue applications
- mediastinal and thoracic lesions and abnormalities;
- cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips;
- pilonidal cyst removal and repair;

Indications for Use

510(k) Number (if Known): K040234

Device Name: LaserPro® CO_2 Carbon Dioxide Laser System

Indications For Use: Continued from previous page:

Orthopedics

Incision, excision and vaporization of soft tissue in orthopedic surgery. Applications include:

- **Arthroscopy**
  - menisectomy;
  - chondromalacia;
  - chondroplasty;
  - excision of plica;
  - partial synovectomy;
  - ligament release (lateral and other);
- **General**
  - debridement of traumatic wounds;
  - debridement of decubitus and diabetic ulcers;
  - microsurgery;
  - artificial joint revision;
  - PMMA removal

Dental Oral Surgery

- Incision, excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- gingivectomy- removal of hyperplasias;
- gingivoplasty;
- incisional and excisional biopsy;
- frenectomy (frenum release);
- treatment of ulcerous lesions, including aphthous ulcers;
- incision of infection when used with antibiotic therapy;
- excision and ablation of benign and malignant lesions;
- homeostasis;
- operculectomy;
- crown lengthening;
- removal of soft tissue, cysts and tumors;
- oral cavity tumors and hemangiomas;
- abscesses;
- extraction site hemostasis;
- salivary gland pathologies;
- preprosthetic gum preparation;
- leukoplakia;
- partial glossectomy;
- periodontal gum resection